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No. 87-498

In the Supreme Court of the United States

OCTOBER TERM, 1987

KEVAN BERKOVITZ, ET AL., PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE UNITED STATES

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QUESTION PRESENTED

Whether the discretionary function exception to the Federal Tort Claims Act, 28 U.S.C. 2680(a), bars petitioners' claims that the government was negligent in its 1963 decision to license Lederle Laboratories' Sabin oral polio vaccine and in its subsequent approval of the release of a specific lot of that vaccine.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-27a) is reported at 822 F.2d 1322. The opinion of the district court (Pet. App. 28a-36a) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on June 30, 1987. The petition for a writ of certiorari was filed on September 25, 1987. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Petitioner Kevan Berkovitz contracted polio from Orimune, a Sabin oral polio vaccine manufactured by Lederle Laboratories. Berkovitz, joined by his parents as guardians, filed suit in federal district court alleging that the United States is liable for his injuries under the Federal Tort Claims Act (FTCA) because the government was negligent in licensing Orimune on June 25, 1963, and

because the Food and Drug Administration (FDA) was negligent in releasing the specific lot of vaccine from which Berkovitz received his dose on May 10, 1979.[1] As to the first claim, petitioners allege that the Division of Biologic Standards (DBS), at that time part of the National Institutes of Health, issued a license for Lederle's Sabin poliovirus strain when it had not been tested in accordance with DBS' own regulations, and that DBS failed to require Lederle to show that a particular "seed virus" had been subjected to all required testing and had complied with all regulatory standards. Pet. 4; Pet. App. 4a-5a. On the second issue, petitioners claim that the Bureau of Biologics of the FDA improperly issued a lot release approval, permitting the vaccine containing Berkovitz's dose to be distributed to the public, despite the fact that the virus in the vaccine had been tested and found to exceed the standards for neurovirulence set forth in regulations applicable to live polio vaccines. Pet. 5; Pet. App. 4a-5a.[2]

2. The government moved to dismiss the suit as barred by the discretionary function exception to liability under the FTCA, 28 U.S.C. 2680(a).[3] The district court agreed

[1] Petitioners also claimed in district court that the United States was negligent in failing to withdraw the vaccine from the market and in failing to require the manufacturer to provide adequate warnings. These allegations were dismissed in the district court as barred by the FTCA's "discretionary function" exception, and petitioners conceded the propriety of that dismissal on appeal (Pet. App. 6a n.4). No further review on those issues has been sought.

[2] Since the case was disposed of on the government's motion to dismiss in lieu of an answer, the government has as yet had no occasion to assert its vigorous disagreement with petitioners' factual allegations, which for purposes of this motion must be taken as true.

[3] Section 2680(a) provides that the FTCA does not apply to "[a]ny claim based upon • • • the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused."

that the government was immune from two of petitioners' original claims,[4] but nonetheless concluded that both the licensing of the vaccine and the release of the specific vaccine lot were not "discretionary function[s]" within the meaning of the FTCA. The district court noted that the Third Circuit had already held in *Griffin* v. *United States*, 500 F.2d 1059 (1974), that negligent licensing and release of a polio vaccine were not discretionary functions. The government maintained in its motion to dismiss that *Griffin* had been effectively overruled by this Court's decision in *United States* v. *S.A. Empresa De Viacao Aerea Rio Grandense (Varig Airlines)*, 467 U.S. 797 (1984). The district court declined to consider the effect of *Varig Airlines*, however, noting that, as a reported decision of the Third Circuit, *Griffin* was binding on the district courts in that circuit "no matter how persuasive the arguments may be that *Griffin* is no longer valid" (Pet. App. 33a).

3. At the government's request, the district court certified its decision for immediate appeal to the Third Circuit pursuant to 28 U.S.C. 1292(b). Although rejecting the government's argument that the discretionary function exception applies to all claims arising from the regulatory activities of federal agencies (Pet. App. 12a-15a), the court of appeals reversed in a divided opinion. Concluding that it "need not treat separately the licensing claim and the lot release claim" (*id.* at 15a), the court proceeded to analyze the question whether the government had a nondiscretionary duty to ensure that Lederle followed regulatory standards in the production and distribution of the Sabin polio vaccine (*ibid.*). The court of appeals canvassed the applicable regulations and noted that, while they required the manufacturer to perform certain tests and submit qualifying results to the government, they did not require the government to do anything (*id.* at 18a-22a). The court

[4] See n.1, *supra*.

concluded that, as in *Varig Airlines,* the onus was on the manufacturer to comply with applicable safety standards, while the role of the government agency was " 'merely to police the conduct of private individuals by monitoring their compliance with [the applicable] regulations' " (*id.* at 22a (quoting 467 U.S. at 815)). Because "neither the statute nor the regulations mandate the FDA's choice of how to secure Lederle's compliance" (Pet. App. 22a), the court concluded that the discretionary function exception bars suit for alleged negligence in the government's performance of that role.[5]

ARGUMENT

In our view, the decision of the court of appeals is correct. There is, however, a direct conflict between this decision and a recent decision by the Ninth Circuit. Furthermore, that direct conflict is symptomatic of a broader post-*Varig Airlines* disharmony among the courts of appeals concerning the extent to which the negligent execution of a safety-related regulatory program is subject to suit under the FTCA. Finally, the question presented in this case is important and its resolution may have far-reaching consequences upon the future availability of life-saving vaccines. Accordingly, we agree with petitioners that the Court should grant certiorari in this case.

1. On May 18, 1987, just over a month before the court of appeals' decision in this case, the Ninth Circuit held that the discretionary function exception did not apply to the government's 1963 decision to license the Lederle oral polio vaccine. *Baker* v. *United States,* 817 F.2d 560, 565-566 (1987). The plaintiff in *Baker* alleged that DBS

[5] Judge Higginbotham dissented (Pet. App. 23a-27a), concluding that the government has no discretion to issue licenses for vaccines that have not been tested and found to meet the requirements set forth in the regulations.

negligently violated its own regulations when it failed to require submission of test data before making its licensing decision. The Ninth Circuit relied in part on the pre-*Varig Airlines* cases of *Griffin* v. *United States, supra,* and *Loge* v. *United States,* 662 F.2d 1268 (8th Cir. 1981), cert. denied, 456 U.S. 944 (1982), and distinguished *Varig Airlines,* where "the mandatory regulations governed the conduct of the airline, not the government" (817 F.2d at 565-566). It said that in this case, by contrast, the agency "may not issue a license for manufacturing poliovirus vaccine unless the relevant test data has been submitted," and that the agency thus has a mandatory duty to require the submission of those data (*id.* at 566). The court was unwilling to apply the discretionary function exception to the plaintiff's allegations of "a negligent failure to obey a mandatory regulatory command" (*ibid.*). The government's petition for rehearing with a suggestion of rehearing en banc was denied by the Ninth Circuit on October 15, 1987.

There is, thus, a direct conflict between the Third Circuit's holding that the FDA's Sabin vaccine licensing decision was a discretionary function, and the Ninth Circuit's decision in *Baker* that it was not.[6] The government will shortly file a petition for a writ of certiorari in the *Baker* case. We suggest that the Court grant certiorari in this case, and hold *Baker* pending a decision on the merits here.[7]

[6] In the present case, the court of appeals noted the *Baker* decision and stated that "Berkovitz's complaint can be read as alleging a similar failure to require submission of test data." The court of appeals expressly declined to follow the Ninth Circuit panel's determination on this issue, stating (Pet. App. 18a n.6):

> We do not agree [with the *Baker* determination], however, that the FDA is under a duty to require submission of test data. Rather, the duty to submit test data rests with the manufacturer. *See* 21 C.F.R. §§ 601.2, 610.1, 630.10(b)(4)(1987).

[7] We agree with the Third Circuit that the additional allegation that the FDA was negligent in releasing the lot of vaccine containing peti-

2. This direct conflict between the Third and Ninth Circuits is part of a larger confusion among the courts of appeals as to the proper application of this Court's decision in *Varig Airlines*. In *Varig Airlines*, the Court held that the FAA's program of spot-checking compliance with safety standards, with the primary burden placed on the manufacturer to ensure compliance, "falls squarely within the discretionary function exception" (467 U.S. at 820). "The FAA," the Court noted, "has a statutory duty to *promote* safety in air transportation, not to insure it" (*id.* at 821 (emphasis in original)). Two circuits, however, in cases decided after *Varig Airlines*, nonetheless have imposed liability on the government for negligence in conducting safety compliance checks. See *Collins* v. *United States*, 783 F.2d 1225 (5th Cir. 1986) (decision by Mine Safety and Health Administration to rescind an "Imminent Danger Order" and not to reclassify mine as "gassy" after inspection revealed high methane levels); *McMichael* v. *United States*, 751 F.2d 303 (8th Cir. 1985) (failure of Defense Department inspectors to enforce safety requirements on defense contractor). Both courts distinguished *Varig Airlines* because the inspectors in question had no discretion not "to enforce the detected violations of the safety requirements" (*McMichael*, 751 F.2d at 307; see *Collins*, 783 F.2d at 1230-1231).

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tioner Berkovitz's dose does not materially alter the analysis for purposes of the discretionary function exception, since the regulations which governed that decision, 21 C.F.R. 630.10(b), are almost identical to those in effect when the original licensing decision was made. 42 C.F.R. 73.110(b) (1963).

We note, however, that this additional allegation concerning the lot release decision was not present in *Baker*. Should the Court so desire, it could thus limit its consideration to the precise issue on which there is a conflict – the applicability of the discretionary function exception to the 1963 vaccine licensing decision – either by granting the petition in *Baker* and holding this case pending its resolution or by limiting the grant of certiorari here.

Most courts, by contrast (including a different panel of the Eighth Circuit), have heeded this Court's injunction not to turn agency efforts to enhance safety into government insurance of regulated industries. See, *e.g.*, *Barnson* v. *United States*, 816 F.2d 549 (10th Cir. 1987) (alleged failure of U.S. Public Health Service and AEC to warn uranium miners of, and protect them against, radiation hazards); *Bacon* v. *United States*, 810 F.2d 827 (8th Cir. 1987) (alleged failure of HUD and EPA to warn of dioxin levels during repair of roads at Times Beach under federal block grant); *Merklin* v. *United States*, 788 F.2d 172 (3d Cir. 1986) (AEC inspectors' alleged failure to warn uranium processing plant employees of health hazards discovered during AEC inspections); *Cunningham* v. *United States*, 786 F.2d 1445 (9th Cir. 1986) (alleged failure of OSHA to exercise reasonable care in conducting plant inspections); *Begay* v. *United States*, 768 F.2d 1059 (9th Cir. 1985) (alleged failure by federal agencies to warn of dangers of uranium mining); *Cisco* v. *United States*, 768 F.2d 788 (7th Cir. 1985) (EPA's alleged failure to warn that dirt contaminated with dioxin had been used in residential land fill); *Baxley* v. *United States*, 767 F.2d 1095 (4th Cir. 1985) (FAA's allegedly negligent decision not to regulate or inspect ultralite aircraft); *Shuman* v. *United States*, 765 F.2d 283 (1st Cir. 1985) (alleged negligence by Navy in not controlling use and handling of asbestos by contractor); *Russell* v. *United States*, 763 F.2d 786 (10th Cir. 1985) (alleged negligence by MSHA in inspecting coal mine); *Hylin* v. *United States*, 755 F.2d 551 (7th Cir. 1985) (mine inspectors' alleged failure fully to inspect clay mine); *Feyers* v. *United States*, 749 F.2d 1222 (6th Cir. 1984) (Army's allegedly negligent failure to inspect contractor's operation of government-owned railyard), cert. denied, 471 U.S. 1125 (1985); *General Public Utilities Corp.* v. *United States*, 745 F.2d 239 (3d Cir. 1984) (NRC's alleged failure to warn of possible

equipment defects at Three Mile Island nuclear facility), cert. denied, 469 U.S. 1228 (1985); *Natural Gas Pipeline Co.* v. *United States,* 742 F.2d 502 (9th Cir. 1984) (alleged negligence in FAA inspection and issuance of certificates for aircraft).

Despite the weight of authority in the government's favor, a conflict meriting this Court's attention exists on the question of whether an agency's alleged failure to follow its own regulations in regulating the safety of a given industry can give rise to liability under the FTCA. The decisions in *Collins, McMichael,* and now *Baker* clearly attest to the need for further clarification by this Court of its decision in *Varig Airlines.* The current case provides an appropriate vehicle for that clarification.

3. An additional reason to grant certiorari is the importance of the particular question presented here. In 1963, the government made a considered decision, based on detailed test results from the Soviet Union and elsewhere, to approve use of the Sabin oral polio vaccine to combat the still widespread problem of polio. That vaccine is now administered routinely to virtually all children in the United States, and has all but eliminated incidence of that once-dreaded disease. Each year, however, a small number of persons suffer adverse reactions to the Sabin oral polio vaccine. The *Baker* decision permits those persons to seek damages from the United States based on alleged negligence in the government's decision to approve the vaccine. In our view, such tort suits against the government pose a serious threat to the continued availability of this life-saving vaccine. If a court were to conclude that the government was indeed negligent because it failed to follow its own regulations in licensing the vaccine in 1963, thereby rendering the government liable for all damages resulting from it, the government—if it did not want to become a complete insurer of the vaccine—might have to order its withdrawal pending a new licensing proceeding.

The discretionary function exception was designed to avoid just such dilemmas. *Baker* simply cannot be squared with this Court's holding in *Varig Airlines,* 467 U.S. at 813-814, that "whatever else the discretionary function exception may include, it plainly was intended to encompass the discretionary acts of the Government acting in its role as a regulator of the conduct of private individuals."

The Ninth Circuit's decision also has broad implications for the availability of new drugs and vaccines in the United States, all of which must be approved by the FDA. The court stated, without explanation, that "the [discretionary function] exception should be applied cautiously in the field of drug and vaccine testing" (*Baker,* 817 F.2d at 565). To the contrary, nowhere is that exception more appropriate than here, where the government seeks to walk a razor's edge between overcaution and undue haste, while thousands of lives hang in the balance. This is precisely the sort of policy decision that Congress did not want to subject to "judicial 'second-guessing' * * * through the medium of an action in tort" (*Varig Airlines,* 467 U.S. at 814).

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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